Individual Safety Report

3548378-5-00-01

McNeil Consumer Healthcare

McNeil Consumer Healthcare
Washington, PA 19034-2299

Page ____ of ____

Approved by FDA on 11/15/93

Mfr report #

UF Distr report #

FDA use only

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted] In confidence	37 yrs or Date of birth:	(X) female ( ) male	unk lbs or kgs

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)
( ) life-threatening
( ) hospitalization - initial or prolonged
( ) disability
( ) congenital anomaly
( ) required intervention to prevent permanent impairment/damage
(X) other: none

3. Date of event: 2/99 (mo/day/yr)

4. Date of this report: 06/23/99 (mo/day/yr)

5. Describe event or problem

Consumer alleges that the use of Extra Strength TYLENOL® acetaminophen Gelcaps was associated with ABNORMAL LIVER FUNCTION TESTS (liver level was high). Consumer reports using product chronically for approximately 5 months from 9/98-2/99. According to consumer, routine blood work performed by her physician revealed elevated liver function tests. No specific levels were provided. Additional info received 6/14/99: MD revealed that patient described taking up to 12 Extra Strength TYLENOL (OVERDOSE) on some days.

6. Relevant tests/laboratory data, including dates

routine blood work revealed unspecified increase in liver function tests

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

IBS, spastic colon and stomach, inflamation caused by broken pelvis, degenerative disc disease, bruised kidney, insomnia, panic attacks, depression, GERD, Chrone's disease, lactose intolerance, chronic back pain, abdominal adhesions from multiple surgeries, rectal prolapse; "sensitive" to ibuprofen

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Extra Strength TYLENOL Gelcaps

#2

2. Dose, frequency & route used

#1 1000 mg, qid, po

#2

3. Therapy dates (if unknown, give duration) from/to (or best estimate)

#1 9/98-2/99; approx 5 months

#2

4. Diagnosis for use (indication)

#1 chronic back pain

#2

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

6. Lot # (if known)

#1 unknown

#2

7. Exp. date (if known)

#1 unknown

#2

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A

#2 ( ) Yes ( ) No ( ) N/A

9. NDC # - for product problems only (if known)

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10. Concomitant medical products and therapy dates (exclude treatment of event)

XANAX®, FLEXERIL®, PROZAC®, ELAVIL®, injectable triamcinolone

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)

McNeil Consumer Healthcare
Medical Affairs
7050 Camp Hill Road
Ft. Washington, PA 19034

2. Phone number: 215-273-7303

3. Report source (check all that apply)

( ) foreign
( ) study
( ) literature
(X) consumer
( ) health professional
( ) user facility
( ) company representative
( ) distributor
( ) other:

4. Date received by manufacturer (mo/day/yr): 06/14/99

5. (A) NDA # 19-872
IND #
PLA #
pre-1938 ( ) Yes
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day ( ) 15-day
( ) 10-day (X) periodic
( ) initial (X) follow-up # 1

8. Adverse event term(s)

LIVER FUNC ABNO OVERDOSE

9. Mfr. report number

4180395A

E. Initial reporter

1. Name, address & phone #

AUG - 9 2000

2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
( ) Yes ( ) No		( ) Yes ( ) No ( ) Unk

FDA Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.

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